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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,398	11/13/2001	Holger Bengs	114750.2600	4117

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT 5 PAPER NUMBER

1651

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,398

Applicant(s)

BENGIS ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed October 7, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 21-41 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 25, it is not clear what the recitation "microparticles" means. To the extent it means simply small particles, it is not clear how small the particles must be to be encompassed by the claims. The metes and bounds of "micro" are simply not clear. Also, note that molecules themselves are in fact "microparticles."

All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of error. Note that the rejection under § 112, second paragraph, of the language "prebiotic" has been withdrawn over applicant's argument and in view of the fact that the specification defines "prebiotic" as any digestible substance which promotes growth of

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bacteria in the large intestine. This of course encompasses virtually any nutrient.

With respect to the term "microparticles" however, the portion of the specification cited by applicant as providing a definition (specification page 10, lines 22-36) provides only "expedient" dimensions or "preferred" terminology. This entirely subjective language fails to state positively what subject matter is encompassed by the claims, and what subject matter is not. Short of putting clear numerical values in the claims describing the "microparticles, the rejection must be maintained. Note that microparticles clearly encompasses substances such as the typical powder form of starch.

Claim Rejections - 35 USC § 102

Claims 21, 27-36 and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Henley et al (U.S. Pat. 5,409,542).

Henley describes the production of a resistant starch from linear α -1,4 glucan, said linear glucan being prepared by debranching starch. See abstract. Henley discloses that the glucan does not contain any branch points. See column 3, lines 27 and 28. ("The enzymatic treatment is permitted to continue until **essentially complete debranching** has occurred ...")

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(Emphasis added.) Thus, Henley describes the linear α -1,4 glucan product recited in applicant's claims, clearly meeting the limitation requiring less than 0.5% branch points.

Henley also describes that the linear α -1,4 glucans prepared by debranching are useful as a fiber source when combined with foods. See column 2, lines 2-4. ("This starch product when added to foods will contribute to the total dietary fiber present in the foods.") The molecular weight of the disclosed resistant starches includes values ranging from 17 kD to 156 kD, well within the ranges recited in claims 27-29. Note that although the unbranched amylose products are not prepared using amylosucrase, they are indistinguishable therefrom, since the amylosucrase-polymerized products have an identical chemical structure to the enzymatically debranched products.

Lastly, note that the method recited in claim 41 is inherently disclosed by Henley's disclosure of food compositions containing the linear α -1,4 glucans, since a person orally consuming the glucans would inherently benefit from the preventive effect of the glucans. Moreover, because food inherently contains "medicinal" or "therapeutic" compounds, reading those terms at their most broad, claims 39 and 40 must be included in this ground of rejection. Thus, because Henley

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clearly describes the claimed invention, rejection under § 102(b) is required over the cited claims.

Claims 21, 22, 24, 26, 30-36 and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Zallie et al (U.S. Pat. 5,480,669).

Zallie describes the production of a resistant starch from linear α -1,4 glucan, said linear glucan being prepared by debranching starch. See column 3, lines 11-25. Zallie discloses that the glucan does not contain any branch points. See column 4, lines 13-15. ("The enzymatic treatment is permitted to continue until **essentially complete debranching** has occurred") (Emphasis added.) Thus, Zallie describes the linear α -1,4 glucan product recited in applicant's claims, clearly meeting the limitation requiring less than 0.5% branch points.

Zallie also describes that the linear α -1,4 glucans prepared by debranching are useful as a fiber source when combined with extruded foods including pasta. See paragraph spanning columns 1 and 2; see also Examples I through III, at columns 4-7. Note that flours and pasta inherently contain vitamins, as recited in claim 21. Moreover, because the mixing of the resistant starch and other ingredients will inherently

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result in "enrobing" of some of the compounds present, claims directed to this embodiment must be considered to be anticipated as well. Also, as discussed above, although the unbranched amylose products are not prepared using amylosucrase, they are indistinguishable therefrom, since the amylosucrase-polymerized products have an identical chemical structure to the enzymatically debranched products.

Lastly, as discussed above, the method recited in claim 41 is inherently disclosed by Zallie's disclosure of food compositions containing the linear α -1,4 glucans, since a person orally consuming the glucans would inherently benefit from the preventive effect of the glucans. Moreover, because any of the nutrient compounds present in flours or pasta can be considered "medicinal" or "therapeutic," reading those terms as broadly as possible, claims 39 and 40 must be considered to be anticipated as well. Thus, because Zallie clearly describes the claimed invention, rejection under § 102(b) is required over the cited claims.

Claim Rejections - 35 USC § 103

Claims 21-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al (U.S. Pat. 5,409,542) and Zallie et al (U.S. Pat. 5,480,669) in view of Brown (WO 96/08261).

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As discussed above, each of Henley/Zallie describe the production of resistance starch from linear α -1,4 glucans, and the use of the resistant starch in foods. Note that the two references are applied together, not in the alternative, because each provides distinct teachings about the properties and/or applicability of resistance starch to certain technologies.

Henley/Zallie differ from the claims in that they do not disclose the use of the glucan as a carrier combined with a beneficial agent is bifidobacteria, as recited in claims 23 and 38. However, Brown discloses a pharmaceutical composition beneficial to the gastrointestinal tract, said composition comprising resistant starch and bifidobacteria. See abstract. Brown also discloses that starches containing over %80 amylose (i.e., over %80 linear α -1,4 glucan) are preferred. See, e.g., claim 5 on page 26. Thus, the artisan of ordinary skill, recognizing from Henley/Zallie resistant starch obtained from unbranched α -1,4 glucans are suitable for use as carriers for beneficial agents, clearly would have been motivated to have used Henley/Zallie's resistant starch as carriers for Brown's bifidobacteria. Specific motivation would have been derived from Brown's disclosure of the desirability of combining the bifidobacteria with high amylose starch, the artisan of ordinary skill clearly recognizing that Henley/Zallie's glucans were in

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fact identical to pure amylose, and therefore well within the at least %80 amylose disclosed by Brown as being desirably combined with the bifidobacteria. A holding of obviousness under § 103(a) is therefore clearly required.

Claims 21-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kossman et al (WO 95/31553) in view of Henley et al (U.S. Pat. 5,409,542) and Zallie et al (U.S. Pat. 5,480,669), and in further view of Brown (WO 96/08261).

As discussed in the previous office action, Kossman describes the production of a linear α -1,4 glucan from sucrose, using amylosucrase, and the use of the glucan in foods and pharmaceuticals.

Kossman differs from the claims in that Kossman does not explicitly disclose the use of the glucan in the production of resistant starch. However, as discussed above, each of Henley/Zallie discloses that linear α -1,4 glucans such as amylose are suitable for the production of resistant starch. Thus, even if the artisan of ordinary skill were to consider the resistant starches of Henley/Zallie to be different from the starches recited in applicant's claims because the Henley/Zallie starches were produced by debranching rather than the polymerization reaction of Kossman, the artisan of ordinary

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skill viewing Kossman in light of Henley/Zallie clearly would have been motivated to have produced resistant starch from the linear amylosucrase-polymerized glucans disclosed in Kossman. Moreover, in view of the fact that Brown directly discloses the suitability of resistant starches as carriers for bifidobacteria, such a use clearly must be considered obvious.

All of applicant's argument has been fully considered to the extent applicable to the new grounds of rejection based on prior art set forth herein, but is not persuasive of error. While applicant has amended the claims around the originally applied Kossman patent, it is clear from Henley/Zallie that resistant starch obtained from unbranched α -1,4 glucans was known at the time of applicant's invention, as was the use of said resistant starch in food applications. Moreover, in view of the direct disclosure by Brown of the suitability of resistant starch for the preparation of bifido bacteria-containing gastrointestinal compositions, the claims under examination must be considered obvious.


No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
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FCP